ANNEX I: Needs not covered by the PRECISAÚDE programme

1. Context of the consultation: 5p medicine as a new health care paradigm

The Galician Health Service has been a pioneer in the implementation of large programmes of Public Procurement of Innovation (PPI). Among some of the most relevant milestones achieved, it is worthwhile to highlight the execution of the following projects and programmes:

- Hospital 2050 and *InnovaSaúde*, with a budget of 90 million euros, funded by the *Innocompra* line using ERDF 07-13 funds.
- *Código 100*, with a budget of over 13 million euros, funded by the FID Lines using ERDF 14-20 funds.
- Innova MicroLab, with a budget of over 5 million euros, funded by the FID Line using ERDF 14-20 funds (currently in progress).
- INNOVATRIAL, with a budget of over 10 million euros, tendered by CDTI (Galician Industrial Technology Development Centre) and funded by the PRTR (currently in progress).

Moreover, it has received awards such as:

- National Innovation Award in the PPI category for the programmes of Hospital 2050 and *Innova-Saúde*.
- Best PPI *Amparo Poch* Project, for *Código 100*.
- First Place: European Award for Public Procurement of Innovation.

With the aim to continue in this line of excellence in the field of PPI, the Ministry of Health and the Galician Health Service, through the Galician Agency for Health Knowledge (ACIS by its Spanish acronym) are promoting a new program, *PRECISAÚDE*, which aims to mobilise around 20 million euros that could be co-financed with ERDF funds from POPE 21-27, through the next contest for the FID line of aid from the Ministry of Science and Innovation (MCIN by its Spanish acronym).

As a fundamental requirement of the contest, and with the aim of receiving proposals for innovative solutions from the market, the Galician Health Service is publishing this Preliminary Consultation to the Market (PMC), in which it launches a series of challenges to be contrasted with the market in order to identify possible innovative solutions that respond to the demands.

The context of this consultation is 5P medicine, an approach linked to the application of specific diagnostic and treatment techniques for each patient based on their individual characteristics. This new paradigm is of great importance, as it allows for a more efficient and effective approach for the treatment of different pathologies, while reducing side effects and improving the patient's quality of life.

In terms of personalisation, 5P medicine is based on the analysis of clinical, genetic, environmental, and lifestyle data to be able to design personalised treatments

adapted to each patient's specific needs, which implies greater precision in the diagnosis, a better selection of treatments, and a greater therapeutic efficacy.

Furthermore, 5P medicine also has a positive economic impact on the healthcare system, as it reduces treatment and hospitalisation costs by minimising diagnostic errors and optimising the use of medical resources. This is due to the fact (among other reasons) that a better initial personalisation of the treatments allows avoiding expenses in diagnostic tests and treatments.

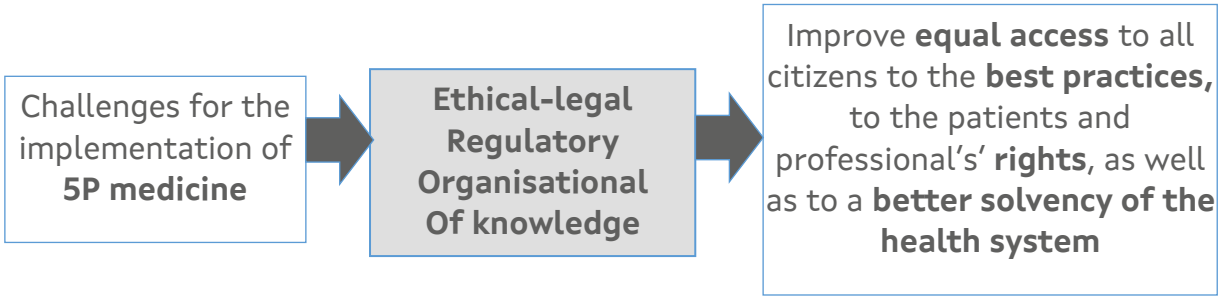
In any case, 5P medicine is much more than the personalisation of diagnosis and treatments, constituting a new paradigm that is embodied as a comprehensive and multidisciplinary approach to health care that combines five key elements:

- Personalisation: 5P medicine focuses on adapting treatments and therapies to each patient's genetic, metabolic, and physiological characteristics in order to improve the interventions' effectiveness and safety, reducing the side effects and optimizing the patient's quality of life.
- Prevention: 5P medicine places special emphasis on disease prevention and the promotion of healthy lifestyles through early interventions and education of healthy habits, seeking to reduce certain diseases incidence and improving the citizen's quality of life.
- Prediction: 5P medicine uses genetic information, clinical data, and risk factors to anticipate the appearance of diseases in susceptible people, which allows the implementation of prevention strategies adapted to the specific needs of each individual or population group.
- Participation: 5P medicine promotes active citizen participation by fostering shared decision-making between the patient and the medical team, ensuring that the patient's preferences and values are considered in the decision-making process.
- Population: 5P medicine considers the population's health needs, developing health policies, and intervention programmes based on epidemiological and demographic data. This approach makes it possible to identify and address health inequalities, guaranteeing equity and justice in the distribution of health resources.

This paradigm shift is transforming clinical and biomedical research, as well as healthcare itself, from a conceptual and methodological point, offering extraordinary opportunities to improve the public health and to reduce the healthcare system costs. 5P medicine allows:

- Early detection of the disease, when it is easier and less expensive to treat it effectively.
- Stratify patients into groups that allow selection of the optimal therapy.
- Reduce adverse drug reactions through a more effective early assessment of individual drug response
- Improve the selection of new biochemical targets for drug discovery.

- Reduce the time, cost and failure rate of clinical trials of new therapies.
- Shift the focus from treatment to prevention, and from illness to wellness.



Numerous autonomous governments have opted to establish a consensual strategy for the development of 5P medicine, as well as to promote its implementation in clinical practice, with equity and guarantees of quality, efficiency, and legality. **The Galician Health Service wants to lead the implementation of this evolution towards 5P medicine, giving great relevance within its new PPI programme, PRECISAÚDE.**

5P medicine is beginning to change the paradigms of medicine, as well as the classification of diseases:

The application of 5P Medicine reports the following **benefits**:

- **Increases the effectiveness and efficiency of medicine**, since it allows use of the most appropriate strategy for each patient, based on the molecular mechanism underlying the disease and the individual's genetic variability.
- **Avoids exposing patients to ineffective medicines,** reducing side effects as well as complications derived from treating them.
- **Allows the development of an industrial sector** of high strategic, health, scientific, and economic value.
- **Greater, more independent, and advanced technological development**, exporting knowledge and technology to a new industrial sector.
- Contributes to the **rationalisation and sustainability of health spending**

But it also implies challenges on two levels:

Ethical-legal and regulatory challenges

- Analysis of the **ethical**, **economic**, **social, and legal implications**, with regard to data protection.
- Guaranteeing the **confidentiality of** sensitive **personal data**, because the biomarker's identification and massive sequencing is based on the collection and analysis of a large amount of information.
- Settling situations regarding **property rights over data and samples**, the validity of the consent that was given, or the right to information.
- Avoiding the risk of **citizens being excluded** based on their genetic data.

Organizational and knowledge challenges

- Incorporating **new professional functions** into the health systems (bioinformatics, physicists, etc.).
- From a scientific perspective, it requires **molecular bases of the diseases**, of the diseases' interactions, and of the interaction between genes and the environment.
- Initiating studies to evaluate healthcare apps, which requires significant **investment and a multidisciplinary approach**.
- Participation of the main scientific societies and to establish the **accreditation of reference centres.**
- **Letting the general population know about this paradigm shift** within the framework of prevention and health promotion activities, which are an integral part of 5P medicine.

2. Priority areas of action

Given that 5P medicine is a broad area capable of deriving into multiple projects with innovative potential, the Galician Health Service has restricted the scope of the PRECISAÚDE project around a series of priority areas:

Innovative simulation systems for:

(R4) Hemodynamic techniques for the treatment of cardiorespiratory arrest and ECMO
(R5) Chronic wound treatment

Innovative solutions based on biomarkers for:

(R1) Early diagnosis, detection of recurrences and/or cancer screening
(R2) Anticipate and monitor the response to obesity treatments
(R3) Early diagnosis and monitoring of mental disorders

Innovative therapy solutions:

(R7) Have new advanced cellular immunotherapies that answer to health problems not covered by market solutions
(R8) Innovative systems for managing the production of advanced therapies

Integrated advanced genomic analysis solutions:

(R6) Have global omics data management platforms that integrate all the relevant information from the clinical history, enabling the creation of a data space for an automated, fast and reliable analysis supported by the use of big data and AI techniques

Alignment with 5P medicine

The priority areas of action established within the framework of the PRECISAÚDE project are clearly aligned with the 5P medicine paradigm. Specifically, the field of **"Innovative solutions based on biomarkers"** for the early diagnosis of cancer, the evaluation of the response to nutritional treatment of obesity, and the early diagnosis and monitoring of mental disorders; it is related to Predictive medicine, since it is based on the use of biomarkers to predict the appearance or evolution of diseases. In the case of early diagnosis of cancer, it could be identified at an early stage, which would increase the chances of successful treatment. In the case of obesity, the patient's response to a specific nutritional treatment could be evaluated, which would allow to optimize it in advance, improving its effectiveness. In the case of mental disorders, signs or patterns could be identified early, which indicate susceptibility in the development of a mental illness or changes in the evolution of patients already diagnosed.

Additionally, this field is also linked to Personalised medicine, since the use of biomarkers allows greater precision in the diagnosis and treatment of diseases. With greater precision in the diagnosis, more specific and personalised treatments could be applied to each patient, whether they are cancer patients, patients with obesity or mental disorders. Finally, it is also related to the population approach, since priority areas have been identified (cancer, obesity and mental disorders) that, together, cover different and highly diverse population groups.

On the other hand, the field of **"Innovative Simulation Systems"** has a clear training focus for the health personnel and even other groups, which could derive in a complementary way, if sufficiently mature solutions were identified, in decision-making assistance systems aligned with the concept of digital twin applied to the healthcare field.

In any case, this area is directly linked to the prediction and prevention dimensions of 5P medicine, since by improving the health professionals training in advanced techniques it is possible to prevent complications and improve the effectiveness of health care. Moreover, it is linked to the personalisation of treatment, since formation and training in specific techniques in different simulated theoretical scenarios can be adapted to each patient's individual needs depending on the circumstances. Finally, in areas such as the treatment of chronic wounds, the recipients would be professionals from the Galician Health Service, Social Health Centres, patients and caregivers; this is in clear alignment with the participatory aspect of 5P medicine.

The field of "**Advanced genomic analysis solutions**" is related to the prediction and prevention aspect of 5P medicine, with a population approach. This is because advanced genomic analysis allows us to accurately identify underlying factors in a broad spectrum of diseases, which in turn facilitates prediction of disease progression and selection of personalised treatments. This is enhanced by the integration with clinical databases and data mining to cross-reference them with

genomic information, making it possible to improve the clinical decision-making and the quality of the treatment offered.

Advanced genomic analysis is also related to Prevention, since it allows early identification of genetic alterations that can lead to a disease and prevent them before they manifest clinically, improving the population's health in general. Finally, it is clearly related to the population approach of 5P medicine, as it allows care for a wide spectrum of diseases, including rare diseases, which are diseases that affect less than 1 in 2,000 people and therefore receive reduced or no attention from the private sector.

Finally, the field of "**Innovative solutions for advanced therapies**" is linked, by definition, to Personalised medicine, since it is based on the personalisation of the treatment of pathologies such as cancer. Specifically, in the case of Chimeric Antigen Receptor T-cell Therapy (CAR-T) and other advanced cellular immunotherapies, cells of the immune system are altered in the laboratory to specifically attack the cancer cells of a particular patient, which allows greater treatment effectiveness and reduction of side effects.

Alignment with the strategic framework of the Galician Health Service

Besides maintaining a clear adherence to the principles of 5P medicine, the established priority areas also involve key elements of the Galician Health Service strategic framework.

On the one hand, in the field of "**Innovative solutions based on biomarkers**" the fields of cancer, obesity and mental disorders have been prioritized; which were included to a greater or lesser extent in the "Health Priorities Plan: 2014-2016".

Furthermore, cancer is a priority for the Galician Health Service, backed by the existence of a specific strategy for its management (Cancer Management Strategy in Galicia 2022-2028 and Precision Oncology Strategy in Galicia), in which principles or courses of action are mentioned that have a perfect place in PRECISAÚDE, such as:

- The extension of the screening coverage programmes for 2028.
- Progress in early detection.
- Biomarkers as a key element to stratify the population at risk.
- Recognition of different key technologies in this regard (liquid biopsy and other functional and molecular imaging techniques, with or without AI).

In relation to obesity, it constitutes an area recognised as relevant by the Galician Health Service, especially among youth. The Zero Obesity Plan is framed in this area as a comprehensive initiative for the prevention and control of obesity in Galicia to reduce its prevalence in the Galician population through preventive and therapeutic measures, promoting healthy eating and physical activity habits and promoting early detection and treatment of obesity and its complications. Among the actions contemplated in the plan are training of health professionals, promotion of healthy lifestyles, improvement of health care, and obesity research.

The aspect of mental disorders is especially related to the "Post-Covid-19 Galician Mental Health Plan (2020-2024)", which recognises the most contemporary research in genomic fields. In fact, derived from this plan, the "Plan for the implementation of pharmacogenomics in psychiatry" was developed, whose execution was entrusted in 2021 by the Galician Health Service to the Galician Foundation of Genomic Medicine. This plan consists of performing a study to improve the dose adjustment of patients with extended-release medications through pharmacogenetic analysis, which would lead to the reduction of adverse reactions in these types of patients.

With regard to the priority area of "**Innovative simulation systems**", the training initiatives have a transversal nature, something evident in the aforementioned "Health Priority Plan: 2014-2016", which contemplates different training areas like the "Strategy Sergas 2014", which included among its principles "*orientation to professionals [...] with a competency-based management system based on training, evaluation and professional recognition*". In any case, the main reference in this regard is undoubtedly the Galician Health Knowledge Agency and, specifically, the "AFEDAP 2023 Training Plan", a clear commitment to the professional development of the staff of the Galician Health Service and affiliated entities to the Ministry of Health and the Galician Health Service, and aims to encourage skills that are essential in the framework of health care.

Additionally, the priority area of "**Advanced genomic analysis solutions**" has a clear link with the Galician Strategy on Rare Diseases (2021-2024), since a key aspect of it is "*research in genomic medicine, with the aim to search for the genes responsible for diseases, understand their mechanisms and improve their diagnosis, prognosis and treatment*". As previously mentioned, the strategic framework of the Galician Health Service recognises the relevance of genomics in the field of mental health, as evidenced by the existence of a "Plan for the implementation of pharmacogenomics in psychiatry" included in the "Post-COVID-19 Galician Mental Health Plan" as well as in the "Galicia Precision Oncology Strategy".

Finally, the priority area of "**Innovative solutions for advanced therapies**" has a clear strategic alignment for the Galician Health Service. Specifically, advanced therapies such as CAR-T are related to the "Cancer Management Strategy in Galicia (2022-2028)" and the "Precision Oncology Strategy of Galicia", which recognizes the need to promote innovation and research in the field of health, establishing specific objectives to improve access to advanced therapies such as CAR-T and to promote collaboration in research and development projects in the health sector. Moreover, the Galician Health Service is investing resources in the creation of the Galician Advanced Therapies Production Centre, which aims to manufacture advanced therapeutic products, including CAR-T therapies, for use in clinical trials and medical treatments, showing the clear commitment to the promotion and access to advanced therapies for the Galician population.

3. Priority challenges in the framework of PRECISAÚDE

Considering the previous prioritised areas of action, the table below summarises the challenges that have been prioritized within the framework of the PRECISAÚDE project:

Challenge	Area
PS-R1: Development and validation of innovative solutions based on rapid, reliable detection and applicable in clinical settings of biomarkers for early diagnosis of cancer, early detection of recurrences in cancer patients, and/or population screening	**Biomarkers**
PS-R2: Development and validation of innovative solutions to anticipate and monitor the response to obesity treatments based on the rapid and reliable detection of biomarkers applicable in clinical settings	**Biomarkers**
PS-R3: Development and validation of innovative solutions for early diagnosis and monitoring of mental disorders based on the rapid and reliable detection of biomarkers applicable in clinical settings	**Biomarkers**
PS-R4: Development and validation of simulation solutions of hemodynamic techniques for treatment of cardiorespiratory arrest and ECMO	**Simulators**
PS-R5: Development and validation of simulation solutions for the treatment of chronic wounds	**Simulators**
PS-R6: Have global platforms for the management of omics data that integrate all the relevant information from the clinical history, enabling the creation of a data space for automated, fast and reliable analysis, supported by the use of big data and AI techniques	**Genomic analysis**
PS-R7: Provide new advanced cellular immunotherapies that respond to health problems not covered by the market needs	**Therapies**
PS-R8: Development and validation of solutions for the integral management of the production process linked to advanced cell therapies	**Therapies**

Regarding the solutions proposed to any of the above challenges, it is necessary to emphasise that they must meet the following requirements:

- Projects with an execution period not exceeding 3 years are sought.
- The proposals submitted must be at an adequate level of technological maturity (see section 5 of this document).
- In addition to aligning with the literal of the challenges, the proposed solutions may include functionalities or complementary solutions, as long as they add value to PRECISAÚDE's strategic framework.
- Market solutions that are currently in the market cannot be proposed.
- All proposals must be conducive to obtaining a comprehensively applicable solution in the hospital environment.

- It is essential that any proposal falls within one of the four priority areas. In the case of the areas of "Innovative solutions based on biomarkers" and "Innovative simulation systems", priority attention will be given to the themes identified in the corresponding challenges, however, innovative solutions may be proposed that, fitting into the general theme of the corresponding area, are not aligned with the prioritized challenges as long as they meet the following conditions.
    - That it is related to 5P medicine
    - That it is linked to the priorities of the strategic framework of the Galician Health Service
- Without prejudice to the additional requirements that may be applicable, the proposals that involve the integration with systems of the Galician Health Service must comply with the requirements in this regard that are established in the documents in force on technical specifications for the integration of the Galician Health Service. (https://www.sergas.es/Recursos-Economicos/Documentacion-especificacions-tecnicas?idioma=es).

In addition to these general requirements, each of the above challenges is explained in greater detail below:

3.1. PS-R1 Innovative biomarker solutions in oncology

Challenge: Provide innovative solutions based on rapid, reliable, and applicable detection of biomarkers in clinical settings for early cancer diagnosis, early detection of recurrences in cancer patients and/or population screening

Background.

Early diagnosis can improve the chances of treatment success and save lives, especially in the most relevant types of cancer among the Galician population in terms of prevalence and mortality, among which we would find:

- Colon and rectal cancer (high prevalence and mortality)
- Gastrointestinal cancer (one of the most frequent cancers, although with a highly variable mortality depending on the type)
- Lung cancer (highly prevalent and the cancer with the highest mortality rate in in Spain)
- Breast cancer, especially metastatic cancer (the most common cancer in women)
- Prostate cancer (high prevalence and low mortality)
- Pancreatic cancer (with high mortality)
- Bladder cancer (relatively prevalent, but with low mortality)

Pancreatic cancer is one of the most lethal, since most cases are diagnosed in advanced stages, which limits the chances of treatment and survival. In Spain, it is the third cause of death from cancer. On the other hand, gastrointestinal cancer is one of the most frequent and varied, with a mortality that depends on the type of

cancer that occurs. In Galicia, it is among the most prevalent types of cancer and represents a major challenge in terms of early detection and treatment.

In this context, the Galician Health Service has pioneered in the use of new detection technologies, such as liquid biopsy, in the Code 100 project, with the aim of improving the early detection of cancer. However, there is an unmet need in relation to the availability of innovative solutions based on rapid, reliable, and clinically applicable detection of biomarkers for early diagnosis of cancer, early detection of recurrences in cancer patients, and/or population screening.

Non-Covered Need.

The lack of methods for early detection and diagnosis in oncology is a major problem due to the low specificity and sensitivity of methods based on imaging and blood biomarkers. This leads to late diagnoses, high costs and low efficiency in population screening campaigns. The development of an intermediate test based on techniques such as liquid biopsy could improve the efficiency of screening, reduce the number of tests such as endoscopies and colposcopies, and improve the stratification of high-risk patients.

In the case of breast and colon cancer, population screening programs already exist, so in these cases the interest in innovative solutions is focused on areas such as the detection of recurrences.

Objective and expected requirements of the solution.

The objective of the solutions requested is to more effectively address the early diagnosis of cancer, population screening, and follow-up of cancer patients (recurrence) through innovative solutions that represent an advance on what exists already on the market at the level of specificity, sensitivity, and integrity in the hospital environment.

In this sense, it seeks to progress in the development of solutions that allow effective and efficient screening for the detection of the disease in asymptomatic people who are in a population at risk, such as in women older than a certain age for breast cancer or in people with a family history of other types of cancer.

The required solution will combine clinical knowledge of biomarkers linked to the types of cancer exposed, with the appropriate technologies for their detection and, in addition, other sources of information, such as interactive questionnaires that collect phenotypic data to assess the participants level of risk to allow an early diagnosis.

In any case, the proposed solutions must meet the following requirements:

- Adequate sensitivity and specificity for the proposed use (screening, early diagnosis, detection of recurrences, etc.)
- The ability to obtain results in less than 5 working days
- Integrability in the hospital environment in terms of simplicity, infrastructure and cost

- Basis on the analysis of samples whose acquisition is minimally invasive, ideally urine, blood or saliva.

3.2. PS-R2: Innovative biomarker solutions linked to the response to obesity treatments

Challenge: Provide innovative solutions to anticipate and to monitor the response to obesity treatments based on the rapid and reliable detection of biomarkers applicable in clinical settings

Background.

According to data from the latest European Health Survey, 39% of the Galician population is overweight and 16.5% is obese, which means that some 444,000 Galicians are obese. This ranks Galicia as the autonomous community with the most overweight population and with the second highest rate of obesity in Spain. These data come from surveys carried out in homes and are self-reported, that is, it is the respondent who indicates their weight and height. Neither weight nor height is measured by trained personnel. According to the data from the ENPE study, and by data on the body mass index, the percentage of overweight people in Galicia amounts to 43.5% and 24.9% with obesity.

These high rates of overweight and obesity will impose a progressive burden for the Galician Health Service, which adds up to the current one due to the aging of the population.

The General Directorate of Public Health of the Regional Government of Galicia has defined a plan with an eight-year temporal horizon that includes 41 actions to achieve 11 different objectives in order to reduce overweight by 15% in the period from 2022-2030.

Moreover, it must be considered that obesity is a disease caused by an excess of total body fat. The body mass index does not reflect reality. A multidimensional approach that includes clinical, biochemical, morpho functional, genetic, and epigenetic assessment is necessary, which, in addition to improving diagnosis, can predict response to treatment and cardiometabolic prognosis.

Non-Covered Need.

There are no known commercial solutions that integrate the detection of biomarkers capable of predicting the response to a treatment in relation to the loss of body fat in obesity, which makes it impossible to predict the patient's response and design optimal personalised treatments.

The absence of this type of solution is a limitation for the clinicians to make a multidimensional assessment of obesity that includes clinical, biochemical, morpho functional, genetic, and epigenetic parameters.

Objective and expected requirements of the solution.

The development of a personalised, non-invasive, rapid, easy-to-use, and accessible test for laboratories and hospitals is sought, aimed to an early pre-diagnosis of the overall treatment response for obesity (nutritional, pharmacological, physical exercise, psychological therapy, surgical). Such tests should be based on biomarkers or techniques that change after loss of total body fat with a high rate of sensitivity and specificity.

The proposed solutions must meet the following requirements:

- Adequate sensitivity and specificity
- The ability to obtain results within 6 hours
- Possibility of automating the technique to analyse more than one sample at the same time depending on the care needs.
- Integrable in the hospital environment in terms of simplicity, infrastructure, and cost

3.3. PS-R3: Innovative biomarker solutions linked to mental disorders

Challenge: Provide innovative solutions for early diagnosis and/or monitoring of the response to treatment of mental disorders based on the rapid and reliable detection of biomarkers applicable in clinical settings

Background.

The recent COVID-19 pandemic has increased mental illnesses, especially in risk groups such as patients with severe COVID-19, families of the deceased, and healthcare workers. There are more than 600 neurological disorders that affect the nervous system, such as major depression, which is the most frequent mental disorder in the general population, affecting between 10-20% of the population. The lack of pathognomonic clinical or biological biomarkers makes correct diagnosis and treatment difficult, which has made it one of the priority lines of research in current psychiatry.

Non-Covered Need.

Diagnosis of mental disorders is based on the assessment of the symptoms and a clinical interview, as there are no commercial diagnostic solutions based on approved biomarkers for their early diagnosis. Similarly, the use of biomarkers linked to monitoring the mental disorders' response to treatment is still an emerging field, with room for the development of innovative solutions. In this sense, detection of specific and sensitive biomarkers in complex biological fluids (such as blood) is essential for the diagnosis and prognosis of many disorders, including psychiatric, neurodevelopmental and neurodegenerative diseases.

Objective and expected requirements of the solution.

The requested solution would be based on the development of an early detection and diagnosis system for mental disorders based on the detection of biomarkers in biological samples (for example, blood and saliva) using solutions that meet the following requirements:

- Sensitivity and specificity according to the proposed clinical use.
- Integrable in the hospital environment in terms of simplicity, infrastructure and cost
- Based on the detection of biomarkers in biological samples for early diagnosis and/or monitoring the response to treatment.

3.4. PS-R4: CRA and ECMO Simulation

Challenge: Have solutions for the simulation of hemodynamic techniques for the treatment of cardiorespiratory arrest and ECMO

Background.

Care for cardiorespiratory arrest (CRA), both of cardiac and traumatic origin, is one of the fundamental axes of the assistance of the Public Foundation for Health Emergencies of Galicia-061 (FPUSG-061 *in Spanish*).

In recent years, techniques have been incorporated that increase CRA survival, such as the use of the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for exsanguinating haemorrhages, and the use of Extracorporeal Membrane Oxygenation (ECMO).

Regarding to the ECMO technique, it is an extracorporeal technique to provide cardiac and respiratory support to patients whose lungs and heart are severely damaged and cannot develop their normal function. Considering that the ECMO machine replaces either vital cardiac or pulmonary function or both, problems cannot arise with its management, and if these problems do appear, they must be solved immediately.

Non-Covered Need.

These techniques require a learning curve both in skills and techniques, as well as in monitoring knowledge, for which there are currently no suitable devices.

It is absolutely essential to have comprehensive patient simulation devices for both performing the techniques and monitoring and controlling the patient, the possibility of performing ultrasound, a complex circulatory system with different circuits and flows, as well as an integrated module for monitoring the patient's hemodynamic and respiratory status.

In regards to the ECMO technique, the ICU nursing staff who spend 24 hours with the ECMO patient must be knowledgeable and trained in this technique to prevent complications and know how to detect them early and to act quickly. Multiple complications can arise in a patient subjected to this therapy and in many of them action must be taken immediately since the ECMO machine replaces the lung and/or the heart function and if there is a failure in the machine that supports these vital functions, the patient will die in a matter of minutes.

It is important to highlight that the survival of an ECMO patient is not only conditioned by the number of cases/years, but also by the training and experience of the centres where it is applied. In experienced reference centres there is a 55%

survival in patients with heart problems and 70% in patients with respiratory problems.

Although the ECMO clinical practice guidelines insist on training to solve complications for a proper management, there is currently no simulator available on the market that meets the requirements set for this challenge.

Objective and expected requirements of the solution.

Comprehensive solutions for simulation of advanced hemodynamic techniques are required for the treatment of CRA and massive internal bleeding. In this sense, due to its educational relevance, a "physical" and tangible simulator is required, without disregard to the fact that it can be complemented virtually, as different critical pathologies and their hemodynamic monitoring can be simulated.

Integration of a large-vessel circulatory system is needed to perform veno-arterial and veno-venous cannulations, as well as the implantation of an aortic catheter at different levels, all through large-calibre vessels. Integration with a circulatory flow management system with fluids is essential, as is the possibility of managing at least four different channels with the capacity to modify impulses and volumes.

All the elements and their joint management must be integrated so that the cannulations are controlled through ultrasound control of the different veins and arteries, and the verification of the correct placement of these is done through vitals monitoring, especially of the blood pressure. Also, if possible, the system should:

- Be a portable device with dual use for both CRA and ECMO.
- Allow complete control of pressures and fluids integration.
- Control the simulator ventilation system that allows changes in respiratory parameters and their influence on the patient's hemodynamic situation.
- Manage the flow of arterial and venous fluids with the possibility of changing frequencies and flows.
- Create complete simulated scenarios that involve everything, from performing the technique to comprehensive management of the patient's respiratory and hemodynamic situation with software control of the different variables and the coordinated response on the actions of the professionals on the simulated patient.
- Simulate all types of complications produced in the hemodynamic and cardiocirculatory behaviour of an ECMO patient, facilitating training of the professional in the correct handling of the equipment.
- Perform an ultrasound of the cannulation area.

Training is especially effective in the prehospital level, since the results are better the sooner these techniques are applied to the patient and by trained personnel who perform the techniques in adequate time. On the other hand, transfer of these patients, especially complex and critical ones, must be assessed continuously through exhaustive monitoring. Because variations and incidence can happen in an acute way, training in early detection and immediate treatment is essential. The latest published

studies (although with only few patients recruited at the moment) indicate 43% survival in the intervention groups compared to 7% in the control group.

With the requested solution, it would be possible to train, under safe clinical conditions, any situation that required the implementation and use of these techniques. Once the learning curve has been overcome, it could be implemented both at the outpatient and inpatient care level.

3.5. PS-R5: Chronic wounds treatment simulation

Challenge: Provide simulated solutions for the treatment of chronic wounds

Background.

The SERGAS 2014 Strategy, the road book of the Galician Health Service, established as a fundamental challenge to achieve safer, more efficient and better-quality care, in which patients and citizens are the centre of all actions.

In this line of action, the General Directorate of Health Care launched the "*Programa Úlceras Fóra* (No Ulcers Programme)" whose objective is to ensure that skin deterioration and tissue integrity ceases to be one of the main health, social and economic problems.

The specific purpose of this programme is to establish a framework to develop and establish the reference lines for everything related to ulcers and wounds, in the search for better quality of life in patients with wounds or who are at risk of suffering them and their caregivers.

The "No Ulcers Programme" is performing a wound knowledge management plan, where the experience and knowledge of our professionals are the key when designing activities, providing training, creating content and managing resources. All of this aimed at the professionals of the Galician Health Service, Social Health Centres, patients and caregivers, who are in charge of covering all the basic needs of the dependent population and together with the professionals are a key element in wounds prevention and treatment.

Non-Covered Need.

Use of new innovative technologies to bring training closer to wound professionals.

The Galician Health Service (Sergas) conducts the centralised purchase of products for wound prevention and treatment. These products form an extensive catalogue that is published and distributed throughout the Sergas network, which brings with it the need for training for efficient wound management.

Objective and expected requirements of the solution.

The objective of this challenge would be to have a tool for simulating the treatment of chronic wounds that covers both their cause and the range of products for their prevention and treatment. Therefore, said solution must:

- Be adapted for its use by different groups (professionals from the Galician Health Service, Social Health Centres, patients and caregivers), which will involve both profiles management and functionalities adaptation and the way of representing the information.
- Be easy to use in different environments without high technological or device requirements.
- Allow to simulate all possible scenarios in the treatment of chronic wounds.
- Integrate all the available products for wounds prevention and treatment in a way that interconnects with the existing information systems to easily update the product catalogue whenever the appropriate information is associated with them.
- Improve based on the received feedback from specific user profiles.
- Provide information underlying the reason why they are considered appropriate, when providing guidelines and recommendations, in order to have adequate traceability of the information shown, improving learning.

3.6. PS-R6: Advanced Cross Genomic Analysis Platforms

Challenge: Provide global omics data management platforms that allow incorporation of all the data derived from omics technologies and that integrate all the relevant information from the patients' medical records, enabling the creation of a data space for a fast and reliable automated analysis of this data, supported by the use of big data and AI techniques and also allowing the possibility of secondary use.

Background.

Galicia has been a pioneer in the implementation of genomic medicine in Spain. It was one of the first communities to have a genetic-molecular diagnostic unit, the Galician Public Foundation of Genomic Medicine. This foundation was a at the forefront in the application of genetic sequencing techniques as an extra diagnostic tool, as well as in doing so in a centralised way for an entire autonomous community, combining the care, research and teaching aspects. It is currently one of the highest-volume activity genomics centres in Spain, with more than 33,000 patients diagnosed per year by its almost 50 professionals, performing not only diagnostic tasks, but also, genetic counselling.

In this way, the Galician Public Foundation of Genomic Medicine provides genomic diagnostic services for all hospitals in the Galician Health Service network for prenatal diagnosis, Mendelian genetic diseases, oncohematology, cancer, and pharmacogenetics.

It also has notable activity in research and genomic services, coordinating the IMPaCT infrastructure, which is the basis on which the entire Spanish personalised medicine strategy is executed.

Non-Covered Need.

Genomic analyses for diagnosis are more and more complex. They require collection, storage, and analysis of a huge amount of information (exomes or complete

genomes), a bioinformatic process of the information (which logically starts from the storage of the same) and a correlation of the genome variations found, selected and prioritised with the data from the medical history in order to reach a diagnostic conclusion and issue a quality report. These actions consume a lot of resources and staff time, resulting in a bottleneck and considerable diagnosis delay.

In this regard, the greatest challenge consists in establishing a network platform that guarantees the management of all the omics resources as well as the optimization of their use and exploitation.

Objective and expected requirements of the solution.

Each advanced molecular analysis performed on a patient generates a need for high storage space, with high security requirements derived from its special sensitivity. One of the main bottlenecks detected for an effective implementation of personalised medicine comes from the huge amount of data that omics technologies require to manage. It is necessary not only to collect the data of the findings and for them to remain accessible in the patient's record, but also that the complete sequences remain available for subsequent analysis. All this information must be able to be retrieved and exploited later and analysed together with other health data (sociodemographic characteristics, patient habits, clinical variables, medical imaging...).

For this reason, it is necessary to develop mechanisms for an automated, fast and reliable analysis and labelling of genomic data using AI techniques, as well as their analysis and integration with clinical data using big data techniques. This will make it possible to reduce genomic information processing times from the moment it is generated to the moment the clinical report is issued, including bioinformatic analysis and clinical-genomic correlation. It also involves storing the data in a secure environment that allows cases to be re-evaluated on a regular basis.

These being the needs of the Galician Health Service, currently there is no commercial technological platform specifically designed to respond in a network to the implementation needs of omics technologies. Therefore, the proposed solutions must be aligned with the following specific requirements:

- Implementation of natural language processing (NLP) tools and data mining of the electronic medical record that allow the extraction of relevant information for cross-checking with genomic data (i.e., translation into HPO/OMOP terminology).
- Integration with the electronic request system for genetic studies.
- Development of a genomic data analysis tool that integrates relevant clinical information to automate the filtering and classification of variants after their annotation by multiple databases.
- Automatic report generation with the option of being personalised integrated into the corporate information system.
- Development of databases with all the detected variants in the processed samples that, on the one hand, allow to perform studies of frequencies of

genetic variants in the Galician population, and on the other hand, allow the automatic re-evaluation of the data on a regular basis as knowledge advances.
- Alerts generation when there is a change in the classification of a variant based on new evidence or when this is found in a gene that has recently been associated with a certain pathology.
- The capacity to improve the automated processes of genomic analysis and connection to clinical information through the feedback given to the system by technicians.
- Allow a corporate policy for omics data management with specific standardised protocols for handling molecular data that define the format and storage system, the quality of the metadata and that guarantee security both in storage and access.
- Establish integration requirements for genomic analysis equipment for its integration with the corporate infrastructure, as well as specific policies regarding advanced processing tools and their integration model.
- Incorporate tools for advanced bioinformatics analysis of omics data that allow the proper processing of samples in NGS.
- Incorporate the healthcare use sequencing data into the health data-lake of the Galician Health Service in accordance with the regulations, to allow its secondary use together with the other records of the different clinical information modalities.
- Analyse the integration model required to create the data repository of omics care as a new data source in the health data lake of the Galician Health Service.
- Establish and implement a single biobanks management and organisation model that allows them to act in a coordinated manner and with a single point of contact for transversal projects in the organisation.
- Establish standardised electronic models for gathering of the informed consent for molecular-genetic analyses.

3.7. PS-R7: New advanced cell therapies

Challenge: Provide new advanced cellular immunotherapies that respond to health problems not covered by the market needs.

Background.

Chimeric Antigen Receptor T-cell Therapy (CAR-T) is a technique to make that the immune cells called T cells (a type of white blood cell) fight cancer by modifying them in the laboratory so that they can locate and destroy cancer cells. CAR-T cell therapy is also sometimes described as a type of cellular gene therapy because it involves altering genes within T cells to help fight cancer.

This type of treatment has meant a paradigm shift in cancer treatment, since it is obtaining results in haematological cancer remission between 50% and 80%. The development and approval of new CAR-T therapies, and other gene and cell

therapies, represent great future expectation for the treatment of disease refractory to cancer treatment as well as in other immune-based pathologies and rare diseases.

In 2020, the Galician Regional Government authorised the initiation of an advanced cell therapy production centre, whose objective is to increase accessibility in the Galician Health Service to advanced cell therapies, especially CAR-T, which is currently in the final activation phase.

Initially, it was planned to start the production under a clinical trial of a biospecific CAR-T medicine, but the plan to put it in operation and consolidation foresees a development pipeline that can be increased both through the constitution of the Cooperative Translational Research Unit in Advanced Therapies of Galicia, as well as collaborations with other organisations open to co-development projects.

Non-Covered Need.

Despite the explosive growth of new biological or biotechnological-based therapies in recent times, there are different types of cancer, immune-based or degenerative diseases for which there are no authorized medicines or that are in the advanced phase of the clinical trial. They constitute an area of unmet clinical need where advanced cell (immune)therapies have a high potential to contribute.

Therefore, the development of different advanced cell (immune)therapies that can be integrated into a clinical programme of cell therapies that provide a solution to the main health problems to be addressed by the Galician Service is identified as the first need not covered by Galician Health Service.

Development of a project with these characteristics is highly complex It is possible to focus on two different stages of the medicine's life cycle, each one of them with a risk inversely proportional to its complexity: preclinical or clinical in early phases. At the same time, the proposal has another high-risk component due to dependence on the market's response capacity, which at the state level is in its incipient and immature phase, both at the industrial and academic levels.

Objective and expected requirements of the solution.

The main objective for this challenge is to identify and integrate relevant agents in the development programme of advanced cellular (immune)therapies for the co-development of new solutions that allow it to be maximised, ensuring equal access under safe conditions. To achieve this, it is required, on the one hand, the pre-commercial development of new advanced therapy medicines and, on the other, a computerized system for the comprehensive management of the programme that makes it possible to guarantee the conditions of traceability, quality, and integral safety.

The new advanced cell (immune)therapies should cover market failures in areas such as:

- Haematological cancer
- Solid tumours

- Immune diseases
- Chronic and degenerative diseases

As mentioned above, the development of solutions will be explored at two different stages of the medicine life cycle:

- Preclinical development phase, which should have at least demonstrative results in a relevant cellular model and, preferably, preliminary data in a relevant animal model.
- Early clinical development phase, where the cell model demonstrative scenario must be complete and conclusive, the animal model with advanced results and, preferably, there must be preliminary results in donor cells.

The proposed development must be developed within the PRECISAÚDE project schedule, so it cannot exceed three years, including the time to obtain the necessary authorisations from the regulatory bodies.

The Galician Health Service will contribute to the project's transfer and production capacity in a GMP environment through its Advanced Therapies Production Centre, as well as the possibility of developing the early preclinical phase in the hospital centers of its network that it dictates. Therefore, the production requirements of the proposed therapies must be compatible with the available clean room infrastructures.

3.8. PS-R8: Innovative systems for managing the production of advanced therapies

Challenge: Development and validation of solutions for the integral management of the production process linked to advanced cell therapies.

Background.

Chimeric Antigen Receptor T-cell Therapy (CAR-T) is a technique to make that the immune cells called T cells (a type of white blood cell) fight cancer by modifying them in the laboratory so that they can find and locate cancer cells. CAR-T cell therapy is also sometimes described as a type of cellular gene therapy because it involves altering genes within T cells to help fight cancer.

This type of treatment has meant a paradigm shift in cancer treatment, since it is obtaining results in haematological cancer remission between 50% and 80%. The development and approval of new CAR-T therapies, and other gene and cell therapies, represent great future expectation for the treatment of disease refractory to cancer treatment as well as in other immune-based pathologies and rare diseases.

In 2020, the Galician board authorized the initiation of an advanced cell therapy production centre, whose objective is to increase accessibility in the Galician Health Service to advanced cell therapies, especially CAR-T, which is currently in the final activation phase.

Initially, it was planned to start the production under a clinical trial of a biospecific CAR-T medicine, but the plan to put it in operation and consolidation foresees a development pipeline that can be increased both through the constitution of the Cooperative Translational Research Unit in Advanced Therapies of Galicia, as well as collaborations with other organizations open to co-development projects.

Non-Covered Need.

In order to guarantee the correct deployment of this advanced cell therapy production programme in the Galician Health Service, with different medicines in different stages of development in concurrent production and service to different centres of the network, guaranteeing the regulatory requirements of safety, quality and traceability imposed by the regulations, a second need not covered by the market is detected in the development of a pharmaceutical production management computer system, which meets the requirements of the correct manufacturing standards and allows full traceability of the process, integrating it into the systems of corporate information.

The development of computerised medicine management systems according to GMP and guaranteeing adequate traceability conditions is oriented towards industrial production processes, with different functionalities and at a higher degree of scaling than that of a hospital programme, even if it is centralised. At the same time, in autologous production processes, traceability is divided between the cell therapy process in the health system and the manufacturer's production process. No comprehensive solutions have been detected on the market that allow complete traceability from patient to patient, guaranteeing the management of all information under the corporate infrastructure of the health service.

Objective and expected requirements of the solution.

The main objectives of the project to develop a computerised system for the comprehensive management of medicine production within the Galician Health Service are:

- Total traceability of patients, initial materials, parameters of production, quality control and products.
- Simplification of documentation and management tasks.
- Automation and integration of data coming from the production equipment.
- Integration with the information systems of the blood bank laboratory where the patients' apheresis are generated.
- Support for the developed processes in an environment of correct manufacturing standards, the tool itself fulfils its requirements.
- Coding according to the ISBT for ATMPS.
- Complete documentation of the pharmaceutical quality system records (including those related to facilities and people).
- Flexibility to accommodate other production processes under GMP, at least PET radiopharmaceuticals.

4. Expected benefits

Although the entire Galician society would benefit in terms of expectancy and quality of life, the PRECISAÚDE project will benefit multiple specific groups profiles, among which the following stand out:

- Cancer patients, who would have access to mechanisms for early diagnosis and better monitoring of possible recurrences, as well as new advanced treatments such as CAR-T that open up new perspectives in terms of personalised treatment.
- People with obesity problems, in the form of mechanisms that anticipate the response to nutritional treatment, improving the design of more effective and personalised treatments.
- People with mental disorders, who could receive earlier and more accurate diagnoses of their pathologies, as well as better monitoring of the response to medication, optimizing their adjustment.
- Professionals from the Galician Health Service, Social Health Centres and caregivers, who would have access to new training tools that allow them to respond in a more rapid and precise manner.
- People with any of the multiple pathologies in which genomic factors influence, especially diseases called "rare" that due to their low incidence do not receive care from the private sector.
- The patients' relatives and their environment, because an improvement in the quality of care has positive effects on the patients' environment.
- Older patients or patients with complex treatment regimens will be able to ensure that they are correctly following the regimen without intervention on their part.

In addition to the specific benefits for each of the groups discussed above, the 5P medicine project could also have a positive impact on other important aspects of the Galician health system, such as:

- Reduction of the care load: by providing faster, more rapid and personalised health care, the care load in health centres could be reduced, which could translate into greater system efficiency and waiting times reduction.
- Improved management of resources: the use of advanced technologies for diagnosis and personalised treatment could contribute to a better management of healthcare resources, avoiding unnecessary tests and ineffective treatments.
- Research promotion: the 5P medicine project would imply the development and application of innovative technologies and treatments in the field of personalised medicine, which could have a positive impact on medical research and the advancement of scientific knowledge.

The magnitude and nature of the benefits achievable with the PRECISAÚDE project may be outlined more precisely once the solutions that are feasible to develop are contrasted through this consultation.

5. Technology Readiness Level (TRL)

The technology readiness level is a key concept in PPI projects. In this regard, the use of the Technology Readiness Level (TRL) is established within the community framework as an indicator to assess the technological readiness of a product or service, and determine its ability to meet the end users' requirements. The TRL is based on a technology readiness scale developed by NASA in the 1990s, and adopted by the European Commission in 2014 as part of the Horizon 2020 programme.

In the ICC context, the TRL is an important tool to assess the technical feasibility of innovative solutions and their fit in its different modalities. For this reason, it is an important aspect in the framework of this consultation in respect of which entities are required to focus the highest level of fidelity and transparency. In this sense, within the framework of the H2020 BRIDGE2HE project, a tool has been developed for the self-assessment of a project. This tool is available in the following URL and may be useful for entities that wish to join this consultation with greater guarantees when it comes to aligning with their approach:

https://horizoneuropenPCPortal.eu/store/trl-assessment

The scale of TRLs goes from 1 (concept) to 9 (commercial solution in the market), the most relevant for the purposes of the PPI projects are those that go from TRL 4 to 9 as indicated below:

- TRL 2-3: too incipient for PRECISAÚDE; it is necessary to improve the degree of evidence to be able to participate in a contest. In any case, a TRL-3 with very creditworthy results could be a candidate for a PCP focused on very early phases.
- TRL 4/5: suitable for PCPPCP or AFI, the fit in the final project definition would depend on the convergence of the existing technologies in the market in terms of maturity, being relevant the fit of the development route with the PRECISAÚDE project term and a TRL of conclusion with sufficient value for the organization.
- • TRL 6/7: suitable for PPITPPIT; if anything for the medicine's development project and MD or IVD with moderate to high-risk classification, they could fit in a late phase PCPPCP or AFI project.

6. PPI modalities

The previously described level of maturity as a starting point for projects derived from PRECISAÚDE, limits the nature of subsequent tenders to three possible modalities:

- Pre-commercial public purchase (PCPPCP)
- Association for Innovation (AFI)

- Public purchase of innovative technology (PPITPPIT)

In the first two cases, the starting point for the project will be technologies with a TRL between 4 (validation in a laboratory environment) and 6 (demonstration in a relevant environment). Likewise, both the object of the pre-commercial public purchase contract and the first phase of the association will consist of a research and development service; being able to develop the association contract for innovation in the contracting of the supply of a commercial version of the developed solution. In this sense, when responding to the form in **ANNEX II**, it is considered especially important to consider the following aspects:

- The budget for phase I of R&D of the project must reflect that its main objective is R&D services, and not supplies. Therefore, the expense items must be consistent with this approach. In any case, the developed prototype may remain in the possession of the Galician Health Service for research purposes.
- When indicating the budget and phases of the project, it is important to differentiate between phase I of R&D necessary to develop the corresponding technologies and obtain a fully functional prototype, and phase II of deployment of the solution.
- Regarding phase II of deployment, and depending on the nature of the project, the scope of the budgeted supply will be indicated.

With regard to the PPITPPIT, the proposals must have a starting TRL equal to 7 (demonstration in an operational environment), with the project focusing on adapting the technologies already tested in a real environment to the context of the project to verify its operation and performance (TRL 8) take it to market as a commercial solution (TRL 9). In this case, when responding to the form in **ANNEX II**, the budget for phase I of R&D of the project will be ignored (since it does not exist) and the budget for the deployment phase will be reported directly, which will correspond with the supply of the solution.

7. Intellectual and industrial property rights

PPI projects are initiatives in which the public buyer and the awardee entities share risks and benefits, with the management of intellectual and industrial property rights (IPR) resulting from the project being a central aspect. In this sense, the natural equilibrium usually implies that the public buyer finances all or a large part of the development, in exchange for which it obtains an unlimited license of the results (including its modification) and sometimes royalties on future income or, in some cases of PCPPCP projects, the ownership of the prototype test (in PPITPPIT or ATI projects, supplies included implicitly in the contract are naturally included).

It is relevant to differentiate at a legal level two study cases differentiated by the obligations imposed in each case by the regulatory framework:

(1) The PCP projects articulated outside of Law 9/2017, of November 8th, on Public Sector Contracts by virtue of its article 8.

(2) The rest of the PPI initiatives within the scope of application of Law 9/2017, of November 8th, on Public Sector Contracts (essentially, AFI and PPIT).

In the second case, there is a wide margin of freedom, given that the regulatory framework for public contracting does not extensively regulate the management of DPIs. In any case, similar clauses to those that we will see below for the first case are usually established.

In the first case, the provisions of commission communication 2022/C 414/01 on the framework for state aid for research and development and innovation[1] apply. Specifically, in PCP projects promoted outside of Law 9/2017, of November 8th, on Public Sector Contracts, the following circumstances must occur:

a) The selection procedure must be open, transparent and non-discriminatory, and based on objective selection and award criteria specified in advance in the tender procedure.
b) The foreseen contractual agreements must outline all rights and obligations of the parties, in particular those regards to DPI, and are available to all bidders interested in advance in the bidding procedure.
c) The procurement does not grant any participating provider special treatment in the final products or services supply of commercial volumes to a public purchaser in the Member State in question.
d) One of the following conditions is met:

- All results that do not result in DPI can be widely disseminated, for example by publishing, teaching or contributing to standardisation organisations in a way that allows other companies to reproduce them, and all the DPI are transferred entirely to the public purchaser.
- Any service provider to whom the results that generate DPI are transferred is obliged to grant the public purchaser unrestricted access to these results free of charge and to grant access to third parties, for example through non-exclusive licences, in market conditions.

In particular, in relation to DPIs, it is important to note that the following circumstances must be met: (1) that the specification details all the rights and obligations regarding DPIs and; (2) considering the will of the public buyer to promote private innovation, that the assignment of the generated DPIs to the winning bidder will mean the need to "grant access to third parties, for example through non-exclusive licences, under market conditions". This scenario is mentioned of the two foreseen in the communication, because it is the usual one in PPI projects. It is for all of the aforementioned that, within the framework of this consultation, specific issues are included in the form in **ANNEX** II in this regard for the purposes of establishing in the bidding conditions *ex ante* specifications of access to the intellectual properties

[1]https://eur-lex.europa.eu/legal-content/ES/TXT/HTML/?uri=CELEX:52022XC1028(03)&from=EN

that are generated, that are reasonable, covering, at least, non-exclusive licenses to third parties in modalities of fixed royalties or as a percentage of the sales.

Additionally, other issues related to the possible clauses of future specifications that regulate contracts are also included in the form of **ANNEX II**, such as:

- The possibility of co-financing the project, this is, the contract does not remunerate 100% of the cost as economic compensation for attributing ownership of the DPII generated by the winning bidders.
- The possibility of establishing royalties in favour of the public buyer, understood as a participation in the benefits of the future exploitation of the DPIs resulting from the project, during a period of 3 years.

On the contrary, the following clauses are considered mandatory, so they will be transferred to the corresponding specifications:

- Grant, in favour of the Galician Health Service, unlimited access to the research results free of charge for its use by the contracting administration and its autonomous public sector.
- Grant in favour of the Galician Health Service, an irrevocable and unlimited license for everyone, fully paid, without copyright, and until the expiration of the respective DPII including pre-existing DPIIs.
- Grant access to third parties through non-exclusive licenses under market conditions, understood as those derived from the contrast with the market within the framework of this consultation.
- Return the generated DPII in the project in the event that they cannot be exploited by the executors themselves or are used to the detriment of the public interest, they are transferred to the contracting administration.

Finally, with regard to intellectual properties that could serve as a starting point for some of the challenges posed by the PRECISAÚDE project, the Galician Health Service is the owner or co-owner of the following patents, and any entity interested in licensing them can contact via email at: Precisaude@sergas.es:

- P3908841A1 - IN VITRO METHOD FOR THE DIAGNOSIS OR PROGNOSIS OF NEURODEGENERATIVE DISORDERS
- EP21382469 - METHOD FOR MONITORING OR PREDICTING WHETHER A PATIENT SUFFERING FROM OBESITY IS RESPONDING OR WILL RESPOND TO A VERY-LOW-CALORIE KETOGENIC DIET (VLCKD)
- EP23382220 - DIAGNOSIS, MONITORING OR PROGNOSIS OF DIABETES OR PREDIABETES
- P201730798 - IN VITRO METHOD FOR DETECTING TUMOR GROWTH AND DIAGNOSING OR PROGNOSTICATING THE RISK OF METASTASIS IN A HUMAN SUBJECT THAT HAS BEEN DIAGNOSED WITH UVEAL MELANOMA

- EP18382013 - Use of the TAS1R3 protein as a marker for therapeutic, diagnostic, and/or prognostic purposes for tumours that express this protein
- P201930743 - COMPOUNDS AND METHODS FOR CANCER TREATMENT
- EP21382448 - IN VITRO METHOD FOR THE DIAGNOSIS OR PROGNOSIS OF BREAST CANCER
- EP22383026 - PERSONALISED IMMUNOTHERAPY IN RENAL CARCINOMA
- EP23382104 - Fragments of the N-Terminal domain of GSDMB for the treatment of cancer
- EP23382269 - OBESTATIN FOR USE AS ANTINEOPLASTIC AGENT IN THE TREATMENT OF PANCREATIC CANCER
- EP23382377 - IN VITRO METHOD FOR PREDICTING CANCER PATIENT RESPONSE TO PD-1 AND/OR PD-L1 INHIBITORS

8. Roadmap and budget for the PRECISAÚDE project

This consultation does not imply any obligation from the Galician Health Service regarding the completion of future tenders, being a prior mechanism to them for transparent dialogue with the market agents with the aim to their subsequent configuration. In any case, the current tentative and non-binding plans of the Galician Health Service regarding the PRECISAÚDE project contemplate the following stages:

- Publication of the preliminary market consultation and deadline for submitting documentation: closing of the CPM on July 17th, 2023.
- CPM launch event on June 22nd, 2023 in the assembly hall of the Ministry of Health.
- Analysis of the documentation received, individual interviews to clarify the pertinent aspects, publication of the corresponding report and, if deemed pertinent, the demand map with the plans of the Galician Health Service regarding this challenge: between July and September 2023.
- Possible publication of the tenders derived from the consultation: during 2024.
- Possible execution of project development: between 2024 and 2027.

The current consultation has as an objective both to verify the viability of the final objective of the consultation, as well as to plan the possible subsequent tenders. In any case, the Galician Health Service does not assume any obligation to undertake the contracts suggested in this roadmap, being the same attempts and being in any case conditioned to the procurement of funding within the framework of the FID Line of the Ministry of Science and Innovation of Spain.

At the budget level, a maximum of 20 million euros is considered for the PRECISAÚDE Innovation Plan.